ORIGINAL INVESTIGATION

The Debate Over Research on Stored Biological Samples

What Do Sources Think?

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Background: The debate over informed consent for research on stored biological samples has enormous scientific implications. Unfortunately, there are no data on individuals' attitudes regarding when their consent should be obtained for such research.

Methods: Data were gathered using a telephone survey of 504 individuals living in the United States. Two cohorts were studied: (1) individuals who had participated in clinical research and contributed biological samples and (2) randomly selected Medicare recipients.

Results: Of the respondents, 65.8% would require their consent for research on clinically derived, personally identified samples; 27.3% would require it for research on clinically derived samples that are "anonymized." For research-derived samples, 29.0% of the respondents would require their consent if the samples retain personal identifiers; 12.1% would require it if the samples are anonymized before the research is conducted. Also, 88.8% would want to be informed of results of uncertain clinical significance, and 91.9% would not impose greater safeguards on future research on a different disease.

Conclusions: Current practice and policy recommendations regarding research using stored biological samples may be inconsistent with sources' preferences in several respects. In particular, it appears that most sources want to control whether their samples are used for research purposes, are not concerned with the particular disease that will be studied, and want to receive results of uncertain clinical significance. Follow-up research will be needed to assess the generalizability of the current data.

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RECENT ADVANCES in genetic and biomedical technologies have dramatically increased the scientific value of the hundreds of millions of human tissue and blood samples stored in laboratories across the country and around the world.[1,2] This increased value has engendered a continuing debate over whether investigators should be required to obtain individuals' informed consent before conducting research on stored biological samples.[3-9]

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Most stored biological samples were obtained during clinical care, for instance, following clinically indicated surgery. Other samples were obtained as part of individuals' previous research participation. Stored biological samples may be identified (linked to personal identifiers) or anonymous (not linked to any personal identifiers).

The principal risks of research on stored biological samples involve unwanted information flow. Such research may reveal facts about sources and their futures that they did not know and would not want others—employers, insurers, or family members—to know. Assessment of research on stored biological samples is difficult because there are no data on the magnitude of these risks. Moreover, most guidelines focus on clinical research that involves direct interaction with people. For instance, the Declaration of Helsinki refers to research "on" humans and research "involving" human subjects.[10] It is often unclear to what extent these guidelines apply to research on stored biological samples.

In contrast, the US federal regulations ("Common Rule") explicitly exempt research on stored biological samples from review by institutional review boards and other regulatory safeguards, provided the sources cannot be "identified directly or through identifiers linked to the samples" (CFR §46.101). On this basis, some commentators argue that investigators need not obtain consent for research on stored biological samples that will be stripped of personal identifiers, or "anonymized." According to the American Society of Human Genetics (ASHG), anonymizing samples protects sources from risks and thus "eliminates the need for recontact to obtain informed consent."[7]

PARTICIPANTS AND METHODS

STUDY POPULATION

To avoid the need to recontact sources, many investigators now obtain consent for future research at the time biological samples are obtained. As a result, the debate over whether sources' consent should be required for research on stored biological samples principally concerns individuals who contributed samples more than 10 years ago. To assess these sources' views, we targeted older individuals who, as part of a research study, had provided biological samples that were stored for future research.

The present data were obtained as part of a 30-minute phone survey regarding individuals' attitudes regarding clinical research. Two cohorts were surveyed. First, potential respondents were selected from ongoing clinical research studies of older individuals who have a first-degree relative with probable Alzheimer disease at 4 geographically dispersed US research centers: Stanford University (Stanford, Calif), Duke University (Durham, NC), University of California, Los Angeles (UCLA), and the National Institutes of Health (Bethesda, Md). To participate in these studies, individuals had to be free from Alzheimer disease as judged by the investigators. To assess the generalizability of these individuals' views, a second cohort was randomly selected from a list of 35 million Medicare beneficiaries. Eligibility criteria were (1) at least 50 years old, (2) able to speak and understand English, (3) ability to understand the survey questions, and (4) sufficient hearing to answer questions over the telephone.

Potential respondents were sent a letter explaining the study, along with a postage-paid, self-addressed "opt-out" card, which allowed them to refuse. Those who did not return the card within 2 weeks were contacted. Verbal informed consent was obtained over the telephone by specially trained interviewers from the Center for Survey Research, Boston, Mass. Interviewers used a functional assessment of respondents' cognitive abilities: those who were able to negotiate an interview time and remember the survey questions were deemed competent.

Overall, 504 individuals completed the survey. Of the 263 eligible respondents from the Alzheimer studies, 246 completed the survey (response rate, 93.5%). Of the 551 eligible respondents identified from Medicare lists, 258 completed the survey (response rate, 46.8%).

SURVEY DEVELOPMENT

Survey development occurred in the 7 following steps:

1. Comprehensive literature review
2. Draft survey development
3. Review by experts in survey methodology and genetics research
4. Survey revision
5. Cognitive pretest using in-person interviews with 3 elderly individuals who were participating in clinical research in the Boston area
6. Behavioral pretest with 3 additional elderly individuals who were participating in clinical research in the Boston area
7. Final revision.

The questions devoted to research with stored biological samples investigated the following 5 domains: research experience, provision of biological samples, whether consent should be required for research on stored samples, desire for research results, and sociodemographics.

Respondents' views on whether their consent should be required were assessed in 3 scenarios. Scenario 1 involved clinically derived samples: "Suppose you had surgery two years ago and during the operation your doctor took a sample of your tissue. Now a researcher would like to use that tissue in a research study." Scenario 2 involved research-derived samples: "Imagine you gave permission for a blood or tissue sample to be taken while you were participating in an Alzheimer disease research study. Later, the researcher wants to use this blood or tissue to study a new aspect of Alzheimer disease."

Some have argued that it is more important to obtain consent for additional research on diseases other than the disease for which samples were obtained. To assess this view, respondents who stated that their consent should not be required for additional research on Alzheimer disease were asked in scenario 3 whether their consent should be required "to study a different disease, like diabetes." In each scenario, respondents were asked whether their consent should be required for research using personally identified samples ("with your name attached") and anonymized samples ("after your name and identifying information had been removed from the sample"). For instance, respondents were asked, "suppose the researcher wanted to use your blood to study a different disease, like diabetes, should the researcher have to get your permission to use the leftover blood for that research if your name is still attached to the sample?" Response categories were "yes," "no," "don't know," and "it depends." Finally, respondents were asked whether they would want to be informed and/or want their physicians informed if "the researcher learned something about you but wasn't sure if it might affect your health."

STATISTICAL ANALYSIS AND APPROVAL

Associations of responses with demographic characteristics (age, sex, income, education, race, religion, and research or Medicare cohort) were tested using a multivariate logistic regression model and a Wald χ^2 statistic. An overall test was first performed ($\alpha = .05$) before individual factors were examined. The study was approved by the institutional review boards at UCLA, Stanford University, Duke University, the National Institute of Mental Health (Rockville, Md), and the University of Massachusetts, Boston.

Critics respond that this view misunderstands the reason for obtaining informed consent. Informed consent is important because it allows sources to control whether their samples are used for research purposes. In the words of a US National Institutes of Health–Department of Energy Working Group on Ethical, Legal and Social Implications of the Human Genome Project, "If research is done on a sample for which the source can be identified, that source should be asked for his or her consent."[8]

Research on stored samples also raises a question of whether "sources" should be informed of results of uncertain significance.[11,12] Researchers often do not have a

clinical relationship with sources, and sources may misinterpret research results of uncertain clinical significance. For these reasons, the US National Bioethics Advisory Commission (NBAC) argues that the need to inform sources usually "does not apply to research using human biological materials."[1] Others argue that investigators should provide sources with information gained about them.

These recommendations all depend on claims concerning what appropriate respect for sources requires. Unfortunately, there are no data on individuals' preferences; hence, commentators on both sides of the debate have been forced to base their recommendations on their own assumptions about individuals' preferences. To assess the accuracy of these assumptions, and provide data for the ongoing debates over research on stored samples, we surveyed 504 individuals with respect to the following questions: Do individuals from whom stored biological samples were obtained think their consent should be required for future research? Are these individuals more likely to think that consent should be required when the research concerns diseases other than the disease for which samples were originally obtained? Do they want results of uncertain clinical significance?

RESULTS

Table 1 outlines respondents' sociodemographic characteristics. Mean age was 65.2 years. The Medicare cohort resembled the average elderly American; individuals from the research cohort had significantly higher incomes, more formal education, and more women and were less likely to be retired and more likely to be white.[13] There were no statistically significant differences in the responses to any questions between the research cohort and the Medicare cohort. Hence, these groups were collapsed for purposes of analysis.

Table 2 provides respondents' views on whether consent should be required for research on clinically derived (scenario 1) and research-derived (scenario 2), stored biological samples. For both clinically derived and research-derived samples, respondents who stated their consent should not be required when the samples retain personal identifiers are reported as believing that their consent should also not be required when the samples will be anonymized. **Table 3** provides respondents' views on whether consent should be required to use samples for additional research on a different disease. None of the sociodemographic factors considered reached statistical significance. Finally, 88.8% of all respondents want to be informed and 82.1% want their physicians informed of research results of uncertain clinical significance.

Multivariate analysis revealed that older individuals (odds ratio, 1.43; 95% confidence interval, 1.01-1.92) and nonwhites (odds ratio, 2.56; 95% confidence interval, 1.23-5.30) were significantly less likely to think that consent should be required for research using clinically derived samples that retain personal identifiers. Otherwise, there were no significant associations between individuals' responses based on their sex, income, education, or whether they had previously participated in clinical research.

Table 1. Respondent Sociodemographics*

Characteristic	Overall (N = 504)	Enrolled in Research on Alzheimer Disease (n = 246)	Medicare Beneficiaries (n = 258)
Sex			
Male	197 (39.1)	82 (33.3)	115 (44.6)
Female	307 (60.9)	164 (66.7)	143 (55.4)
Age, y			
50-54	38 (7.5)	36 (14.6)	2 (0.8)
55-64	131 (26.0)	115 (46.7)	16 (6.2)
65-74	216 (42.9)	66 (26.8)	150 (58.1)
≥75	119 (23.6)	29 (11.8)	90 (34.9)
Employment			
Full time	88 (17.5)	71 (28.9)	17 (6.6)
Part time	69 (13.7)	43 (17.5)	26 (10.1)
Not employed	44 (8.7)	15 (6.1)	29 (11.2)
Retired	302 (59.9)	117 (47.6)	185 (71.7)
Household income, $			
<25 000	107 (21.2)	25 (10.2)	82 (31.8)
25 000-75 000	173 (34.3)	94 (38.2)	79 (30.6)
>75 000	105 (20.8)	88 (35.8)	17 (6.6)
Don't know	39 (7.7)	11 (4.5)	28 (10.9)
Declined to answer	80 (15.9)	28 (11.4)	52 (20.2)
Education			
≤High school	138 (27.4)	21 (8.5)	117 (45.3)
Some college or college graduate	202 (40.1)	110 (44.7)	92 (35.7)
At least some graduate education	163 (32.3)	115 (46.7)	48 (18.6)
Race			
White	456 (90.5)	232 (94.3)	224 (86.8)
African American	22 (4.4)	4 (1.6)	18 (7.0)
Hispanic	8 (1.6)	5 (2.0)	3 (1.2)
Other	10 (2.0)	3 (1.2)	7 (2.7)
Religion			
Protestant	289 (57.3)	134 (54.5)	155 (60.1)
Catholic	106 (21)	44 (17.9)	62 (24.0)
Jewish	56 (11.1)	35 (14.2)	21 (8.1)
Other	16 (3.2)	12 (4.9)	4 (1.6)
None	28 (5.6)	16 (6.5)	12 (4.7)

*Data are number (percentage) of respondents. Because respondents could decline to answer specific questions, percentages may not add up to 100.

COMMENT

Current debates over consent for research on stored biological samples have taken place in the absence of data on sources' own views. The lone exception is the NBAC sponsored "mini-hearings" held in 7 US cities to assess the public's attitudes toward research with stored biological samples.[14] To our knowledge, the present study provides the first systematic assessment of individuals' perspectives on this issue. The results suggest that there may be conflicts between people's attitudes and current recommendations in several important respects.

First, many policy recommendations endorse the same approach regarding consent for research on stored biological samples: either the source's consent is unnecessary or the consent should be obtained whenever possible. The present data suggest that it may depend on the samples in question regarding whether sources think their consent should be required. Two thirds of the respondents believe their consent should be required for re-

Table 2. Consent for Research on Stored Samples*

	Consent Necessary for Clinically Derived Samples?		Consent Necessary for Research-Derived Samples?	
	Personally Identified	Anonymized	Personally Identified	Anonymized
Overall (N = 504)	65.8	27.3	29.0	12.1
Cohort				
In research on Alzheimer disease (n = 246)	68.6	22.8	24.4	8.1
Medicare beneficiaries (n = 258)	63.1	29.8	33.5	15.1
Sex				
Male	60.6	22.3	24.2	7.6
Female	69.0	29.0	32.0	14.3
Age, y				
50-54	83.8†	34.2	21.1	5.3
55-64	69.5	19.8	28.7	12.2
65-74	64.0	28.7	28.2	12.0
≥75	58.9	26.9	33.3	12.6
Income, $				
<25 000	66.7	36.4	34.9	17.8
25 000-75 000	60.9	24.9	21.8	8.1
>75 000	67.6	20.0	26.7	9.5
Education				
≤High school	67.4	37.0	35.8	17.4
Some college or college graduate	61.7	22.8	25.5	11.0
At least some graduate education	69.4	22.1	27.5	8.0
Race				
White	67.2	26.3	28.7	11.0
African American	47.6‡	18.2	31.8	18.2
Hispanic	50.0	25.0	12.5	0

*Data are percentage of respondents who stated their consent should be required for research using 4 different types of stored samples originally obtained from them.

†Older individuals are significantly less likely to state that their consent should be required.

‡Nonwhites are significantly less likely to state that their consent should be required.

search using clinically derived samples that retain personal identifiers. In contrast, just 1 in 8 believes their consent should be required for additional research using research-derived samples that were anonymized.

Most writers assess whether sources' consent should be required based on the risks involved. On this basis, most recommendations endorse very different safeguards for research-derived, identified samples vs clinically derived, anonymized samples. In contrast, essentially the same number of respondents thought their consent should be required in these 2 cases (27.3% vs 29.0%). This result appears to trace to respondents' attention to an issue largely ignored by policy recommendations: did sources ever give consent for the samples to be used for research purposes? Once consent for research purposes has been given, most respondents viewed additional consent for each type of research as unnecessary. This view suggests that once sources give their consent for clinically derived samples to be used for research purposes, it may be possible to regard these samples as equivalent to research-derived samples for the purposes of deciding whether to obtain sources' consent for additional research.

These data also suggest that individuals may not think it is necessary to specify which kind of research will be performed when obtaining biological samples initially. For instance, the model consent form endorsed by the US National Action Plan on Breast Cancer solicits consent for research on cancer and then separately solicits consent for "research about other health problems."[15] Respondents' views suggest that including this distinction on consent forms may complicate the consent process without offering options that subjects find ethically meaningful. It will be important to assess this possibility in future studies. In particular, it will be important to assess whether individuals have concerns about certain research, such as research on drug abuse or mental illness.

Obtaining sources' consent for future research on stored biological samples allows investigators to conduct research on these samples only as long as the risks to subjects do not increase. As a result, investigators and institutional review boards should regularly assess whether future advances in research technologies introduce new risks, thus implying that a new consent may be needed for the riskier, future research. It will also be important to assess the public's understanding of the risks of research on stored biological samples.

Taken together, these data suggest applying a tentative general framework for obtaining consent for research using stored biological samples (**Figure**). Consent should be required for research using clinically derived, identified samples, but waived for additional research using research-derived, anonymized samples. The present data suggest that research using clinically derived, anonymized samples and research-derived, identified samples should be treated similarly. However, these cases also seem the most contentious.

Table 3. Consent for Research on a Different Disease*

	Consent Necessary for Identified Samples?	Consent Necessary for Anonymized Samples?
Overall (N = 504)	15.5	8.1
Cohort		
In research on Alzheimer disease (n = 246)	19.8	7.3
Medicare beneficiaries (n = 258)	11.0	8.9
Sex		
Male	14.1	8.6
Female	16.7	7.8
Age, y		
50-54	26.7	20.0
55-64	19.8	9.1
65-74	12.1	5.9
≥75	13.2	8.0
Income, $		
<25 000	15.9	11.1
25 000-75 000	12.0	8.7
>75 000	15.1	5.3
Education		
≤High school	10.5	8.3
Some college or college graduate	17.2	3.4
At least some graduate education	17.4	12.1
Race		
White	16.3	7.5
African American	13.3	0
Hispanic	0	100

*Data are percentage of respondents who would not require their consent for research on the same disease for which research-derived samples were originally obtained, but would require their consent for research on a different disease.

	Clinically Derived Sample	Research-Derived Sample
Identified Source	Consent Required	Presumed Consent With Opt-Out
Anonymized Source	Presumed Consent With Opt-Out	Consent Not Required

Implications for obtaining consent for research on stored biological samples.

Most respondents stated that their consent is not necessary, whereas a sizable minority thought that consent should be required. Provided that the risks of the research are minimal, one possibility would be to use an opt-out approach. When contact is feasible, investigators could notify sources of the research plan and allow them to refuse, by returning an opt-out postcard, or declining by telephone or e-mail. On this approach, investigators would have to make a good faith effort to inform sources, thus providing the minority who think their consent should be required with the chance to decline. However, consistent with the preferences of the majority, this process would not require investigators to obtain affirmative consent for minimal risk research using clinically derived, anonymized and research-derived, identified samples. Future research will be needed to assess whether it is acceptable to conduct such research without even opt-out consent when contact is not feasible and the risks are minimal.

A number of proposals endorse stricter consent requirements for additional research on diseases other than the disease for which research derived samples were originally obtained. These recommendations appear to conflict with respondents' views that this distinction does not affect whether their consent should be required. However, it is important to note that these data were obtained in response to questions about research on a different disease that was specified as diabetes. Further research will be needed to determine whether sources think that consent requirements should be stricter for research on potentially stigmatizing diseases, such as acquired immunodeficiency syndrome or alcoholism.

Finally, our respondents want to be informed and want their physicians to be informed of research results of uncertain clinical significance. These views contradict much of current practice in genetics research in the United States, as well as NBAC's recommendation that the need to inform subjects does not apply to research on stored biological samples. Future research should assess whether respondents' desire for research results of uncertain clinical significance reflects a lack of appreciation for the difference between clinically validated tests and research assays with no proven reliability or validity. In the meantime, researchers should be aware that the common practice of not divulging results of uncertain significance may prove upsetting to many research participants. In the absence of data that show that providing such information has a negative impact on sources or their families, these results suggest that researchers should consider appropriate mechanisms to allow sources who want such information to obtain it.

In 2 ways, the current data are relevant in determining what policies and recommendations should be adopted. First, a number of recommendations are based on what is required to ensure that research is respectful of sources and their wishes. For instance, whether individuals should be given research results of uncertain clinical significance depends, in part, on whether they want such data. Of course, individuals' views are not the only relevant consideration. In particular, it is also important to assess the amount of effort required to provide this information and the impact that providing it has on sources.

Second, it is widely agreed that investigators should determine what information to provide potential research subjects based on what information a "reasonable" person would want to know, supplemented by any information that specific individuals want. This "combined" standard, for instance, suggests that informed consent documents should describe the kinds of future research that might be conducted on samples being obtained from subjects when a reasonable person would want to know such information and when there is any reason to think that the specific individuals in question would want this information, even though most people would not want it.

Of course, as with any initial data, further study will be required to assess whether the present results can be generalized to other groups. For instance, it will be important to determine whether the present results can be generalized beyond older Americans. Because there were very few minority respondents, the present results may not accurately reflect minority groups' views. Furthermore, older individuals and nonwhites were significantly less likely to think their consent should be required for research using

personally identified samples obtained during clinical care. This result goes against the assumption that nonwhites are more reluctant to participate in clinical research. Given the small number of minorities that were surveyed, additional research will be needed to assess these results. In particular, it will be important to assess whether nonwhites do not view research on stored samples as potentially exploitative in the way they may view research that involves more personal interactions.

Several potential limitations of the present data should be noted. The low response rate for the Medicare cohort may limit generalizability. However, the consistency of responses between the Medicare cohort and the Alzheimer research cohort and the lack of any sociodemographic predictors for most responses suggest no systematic bias. The questions regarding identified samples referred to samples "with your name attached." Future research should consider whether respondents are less likely to require consent for research using samples that are coded so that their names remain connected to the samples, but are hidden from the investigators conducting the research. The family history of Alzheimer disease may raise concerns about the cognitive capacity of the Alzheimer research cohort. However, these individuals were judged free of the disease by Alzheimer disease experts at the time of their research enrollment and periodically during their longitudinal study. Moreover, they were assessed to be functionally competent at the time of the present survey. Finally, respondents may not fully understand the risks and potential benefits of research on stored samples. Thus, the extent to which respondents were willing to allow research on stored samples may be a result of this misunderstanding.

CONCLUSIONS

The present data regarding sources' preferences suggest 5 possible changes in practice and policy on research with stored biological samples:

- For research using clinically derived, identified samples, consider requiring consent the first time the samples are used for research purposes.
- For research using anonymized samples for which sources previously provided consent for research purposes, consider not requiring further consent.
- For further research using identified samples for which consent for research purposes has previously been obtained and anonymized samples for which consent for research purposes has not been obtained, consider not requiring sources' positive consent provided risks are minimal. Instead, consider using presumed consent with opt-out.
- When determining whether sources' consent should be required, it may not be necessary to consider whether the samples were obtained originally for the disease being studied.
- Barring evidence of a significant adverse impact on sources or the ability to conduct important science, researchers should consider developing appropriate mechanisms that allow individuals to obtain research results of uncertain clinical significance.

It is important to note, however, that these recommendations are based on data from a limited sample. Hence, it will be important to conduct future research to assess the generalizability of the present data to other groups and the suitability of these 5 recommendations.

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